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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,938	06/25/2001	Graham P. Allaway	50875-DA/JPW/SHS	9272

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03/11/2008

EXAMINER

PENG, BO

ART UNIT	PAPER NUMBER
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1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/888,938	Applicant(s) ALLAWAY ET AL.	
	Examiner BO PENG	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the amendment received December 10, 2007. Claims 52-56 and 58-60 have been cancelled. Claims 51 and 57 are pending and under examination in this Office action.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **(Prior rejection- withdrawn)** The rejection of Claim 57 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of the amendment to the claim. The rejection of Claims 58-60 is moot in view of the cancellation of the claims.

4. **(Prior rejection-withdrawn-restated)** Claims 51 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The prior withdrawn rejection of Claims 51 and 57 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is restated** after reconsideration of the teachings of the art and the scope of the claims.

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5. Claims 51 and 57 are drawn to a genus of an isolated monoclonal antibody which binds to a CCR5 chemokine receptor on the surface of a human CD4⁺ cell, wherein the antibody inhibits fusion of HIV-I, or an HIV-I infected cell, to the CD4⁺ cell, so as to thereby inhibit HIV-I infection of the CD4⁺ cell, wherein the CD4⁺ cell may be any of a PM-I cell, a primary CD4⁺ T-cell, or a peripheral blood mononuclear cell (PBMC).

In making a determination as to whether a claimed invention has been adequately described, the courts have identified certain elements that may be considered. Among those elements are the knowledge in the particular field, the extent and content of the prior art, the maturity of the technology, and predictability of the aspect at issue. See e.g., *Capon v. Eshhar*, 76 U.S.P.Q. 2d 1078, at 1085 (CAFC 2005). For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

6. Claims 51 and 57 lack adequate descriptive support for the claimed genus of a monoclonal antibody that has the ability to both bind to CCR5 and inhibit HIV fusion to cells because the specification fails to describe any monoclonal antibody that possess such functions, and fails to fully characterize the epitope(s) (or antigen) on CCR5 that are involved in HIV fusion to CD4.

7. The instant specification has disclosed that human chemokine receptor CCR5 on CD4

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cells can mediate HIV fusion to CD4 cells. The specification has also suggested that “an antibody or a portion thereof” against CCR5 to inhibit HIV fusion to CCR5, see e.g. Para 2, p.12. However, the specification has not disclosed any specific antibody that binds to CCR5 and inhibits HIV fusion to a CD4 cell by either its structure and physical and/or chemical property, or any correlation between function and structure.

8. The art provides teachings indicating several forms of uncertainty regarding the operability of species of CCR5 antibody to inhibit HIV fusion to CD4 cells. The art teaches that there is a lack of a general correlation between the antibody binding to CCR5 and inhibiting fusion of HIV. See e.g., Lee *et al.*, J. Biochemical Chem (Exhibit 2, submitted on December 10, 2007). After examining 18 monoclonal antibodies against CCR5, Lee teaches that the ability of CCR5 antibody to bind to CCR5 does not correlate with the ability to block virus infection (See Abstract). Lee shows that only one of 18 monoclonal antibodies that bind to the CCR5 N-terminal region has the ability to inhibit HIV infection of CCR5-positive cells (right col. p. 9621). Thus, the art has demonstrated uncertainty exists in the species of CCR5 monoclonal antibody that can bind and inhibit HIV fusion to CD4 cells. It is noted that Applicant also recognizes and admits such uncertainty exists regarding CCR5 antibody that both binds to CCR5 and inhibits fusion of CD4 cells (see p. 8, Remarks, dated December 10, 2007).

9. However, the instant specification has failed to address such uncertainty. The specification has failed to present any working examples showing any specific monoclonal antibody that both binds to CCR5 and inhibits HIV fusion to CD4, fails to describe a sufficient number of representative species of CCR5 antibodies that encompass the claimed genus, and fails to provide any guidance regarding the specific region(s) or epitopes on CCR5 responsible

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for HIV binding and entry.

10. Because lacking knowledge of specific epitope(s) on CCR5 that are required for HIV entry either in the prior art or the specification, one of ordinary skill in the art cannot envision what the monoclonal antibody is that inhibits HIV fusion, even when accompanied by a method of making a monoclonal antibody to CCR5. Accordingly, it is deemed that the specification fails to provide adequate written description for a genus of CCR5 antibodies and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the alleged invention of a genus of CCR5 antibody that can inhibit HIV fusion.

Claim Rejections - 35 USC § 102/103

11. **(Prior rejection-maintained-extended)** The rejection of Claim 51 under 35 U.S.C. § 102(e) as anticipated by, or alternatively, under 35 U.S.C. § 103 as obvious over Li *et al.* (US 6,759,519), as evidenced by Wu (US 6,528,265), **is maintained** and **extended** to Claim 57. The rejection of Claims 53-56 **is moot** in view of the amendment of the claims.

12. Li *et al.* disclose an antibody that binds the native HDGMR10 (later designated CCR5) chemokine receptor polypeptide (SEQ ID NO: 2, Figure 1). Li teaches that said antibody is polyclonal or monoclonal (col. 18 and claims). Thus, Li's antibody and monoclonal antibody binds to same antigen as the claimed monoclonal antibody.

13. Li also teaches that said antibody is an antagonist of the HDGMR10 (CCR5) polypeptide, which binds to the chemokine receptor but does not elicit a second messenger response such that the activity of the chemokine receptors is prevented (Line 19-27, col. 12, and Claim 57). This functional characteristic is consistent with the functional characteristics of the non-chemokine

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agent, which is a functional equivalent of the claimed monoclonal antibody, described in the instant specification (e.g., p. 14). Thus, Li's antibody and monoclonal antibody seems to have the same functional characteristics as the claimed monoclonal antibody described in the specification.

14. Finally, Li's antibody and monoclonal antibody against CCR5 appears to have the inherent ability to inhibit HIV fusion to CD4 cells. For example, Li teaches that an isolated antibody binds an extracellular portion of HDGMR10, and said antibody is an antagonist of the HDGMR10 polypeptide. As evidenced, Wu teaches that the anti-CCR5 antibody, mAb 2D7, which specifically binds to the second extracellular loop of CCR5 (L.51, col. 37), inhibits HIV entry (Figure 11), and also inhibits the chemotaxis of CCR5 in response to RANTES, MIP-1 α and MIP-1 β (L.60, col.38 to l. 23, col. 39, and Figure 10). Thus, the prior art monoclonal antibody that binds to the CCR5 extracellular domain could also inhibit HIV fusion to CD4 cells as taught by Wu. Moreover, Li discloses a genus of polyclonal and monoclonal antibodies to CCR5 (see claims), which contain many antibodies that specifically bind to different epitopes of HDGMR10 (CCR5), at least one of which would be expected to have the claimed properties. Thus, the antibody of Li's (see especially Claim 21) should possess the functional characteristics recited in the pending claims.

15. Given that Li's antibody and monoclonal antibody against CCR5 possess the same specificity (binds to CCR5), same functional characteristics as the claimed antibody, and appear to have the inherent ability to block fusion of HIV to enter CD4 cells as evidenced, the monoclonal antibody against HDGMR10 (CCR5) of the prior art appear to be either the same or obvious variants of the claimed monoclonal antibody against CCR5.

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16. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibodies of the prior art are not the same as the claimed antibodies. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibodies are different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

In response to Applicant's argument:

17. Applicant argues (1) that Li *et al.* do not disclose any connection between the CCR5 chemokine receptor and HIV entry into a cell, or refer to HIV at all. The Applicant states that Li merely teaches a broad genus of antibodies generated against an isolated HDGMR (CCR5) polypeptide, and that Li *et al.* do not disclose an isolated monoclonal anti-CCR5 antibody which (a) binds to CCR5 on the surface of a cell, and (b) inhibits fusion of HIV-I or an HIV-I infected cell to any of the CD4⁺ cells enumerated in amended Claim 51.

18. In response to Applicant's argument, MPEP indicates that the "Inherent feature need not be recognized at the time of the invention" (MPEP 2112). The discovery of a previously unappreciated property of chemokine receptor HDGMR (CCR5) as a co-receptor for HIV entry does not render the known chemokine receptor CCR5 a new product. The following are citations from MPEP:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim

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patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.” Id MPEP 2112 [R-3]

19. In the present case, the claimed monoclonal antibody against CCR5 is not patentably distinct from those disclosed by Li because the prior art antibody and monoclonal antibody against CCR5 have (1) the same specificity (against the same antigen), (2) the same functional characteristics as claimed, and (3) has the inherent ability to block fusion of HIV to enter CD4 cells as evidenced. (See Para 12-15 above) The new discovery of the use of CCR5 by HIV for viral entry into CD4 cells does not render the known chemokine receptor CCR5 a new product (or a new antigen). Thus, Li’s antibody and monoclonal antibody against the HDGMR10 (CCR5) chemokine receptor should be the same product as an antibody against CCR5.

20. Applicant further argues (2) that inhibition of HIV-1 fusion to a CD4 cell is not an inherent property of anti-CCR5 antibodies (p. 8) because not all antibodies which bind to CCR5 receptor also inhibit fusion of HIV to CD4 cells, thereby inhibiting HIV-1 infection. As evidenced by Vila-Coro *et al.*, (Exhibit 1: (2000) *PNAS* 97(7):3388-3393), Applicant argues that certain anti-CCR5 monoclonal antibodies, produced against the CCR5 extracellular domain, are unable to block HIV-I infection. As evidenced by Lee *et al.*, (Exhibit 2: (1999) *J. Biol. Chem.* 274(14):9617-9626), Applicant also argue that Lee *et al.* tested multiple anti-CCR5 monoclonal antibodies generated to the extracellular domains of CCR5 including monoclonal antibody 2D7

and found that none of the other anti-CCR5 monoclonal antibodies (other than 2D7) consistently blocked HIV infection.

21. In response to this argument, Li has disclosed a genus of antibodies and monoclonal antibodies against the CCR5 chemokine receptor, of which some antibodies or monoclonal antibodies would be expected to recognize the same epitopes as monoclonal antibody 2D7, and thereby inhibit fusion of HIV to CD4. Therefore, inhibition of HIV-1 fusion to a CD4 cell is an inherent property of anti-CCR5 antibodies that recognize the same epitopes as monoclonal antibody 2D7.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. **(Prior rejection-maintained)** The rejection of Claims 51 and 57 under 35 U.S.C. 103(a) as being unpatentable over Cocchi *et al* (1995, Science Vol. 207, p.1811-1815, cited in IDS) and Samson *et al.* (1996, Biochemistry Vol. 35, p.3362-7, cited in IDS), both in view of Berger (US 6,197,578), **is maintained** for the reasons of record. The rejection of Claims 52-56 and 58-60 **is moot** in view of the cancellation of the claims.

24. Cocchi *et al.* teaches that the chemokines RANTES, MIP-1 α , and MIP-1 β were the major HIV suppressive factors to control HIV infection *in vivo* (whole document). Cocchi teaches that recombinant human RANTES, MIP-1 α , and MIP-1 β induce a dose-dependent inhibition of different strains of HIV-1, HIV-2, and SIV. Importantly, Cocchi teaches that antibodies against RANTES, MIP-1 α , and MIP-1 β can completely block the activity of the chemokines to block HIV infection.

25. Cocchi does not teach an antibody which binds to the CCR5 chemokine receptor on a CD4 cell and inhibit HIV fusion to CD4 cells.

26. Samson teaches that CCR5 (also called Chem R13) is a chemokine receptor, and chemokines MIP-1 α , MIP-1 β and RANTES are its natural ligands (Abstract, Para 2, left col. p.3393 and p. 3365-3367 and Figure 3). Thus, the combined teachings of Cocchi and Samson have taught and suggested to one of ordinary skill in the art that blocking the CCR5 receptor on a CD4 cell would inhibit HIV infection.

27. As an analogous art, Berger teaches that one of the human chemokine receptors, CXCR4, on the surface of CD4⁺ cells, is associated with HIV fusion (Figure 1). Berger teaches that the antibodies against CXCR4 block fusion of HIV to a CD4⁺ cell or an infected CD4-positive cell

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(col. 9-12; Example 2, col.20, and Figure 2). Berger also teaches antibodies raised against the 38 amino acid *N*-terminal portion of CXCR4 blocked membrane fusion between the *env*-positive, LAV isolate of HIV-1, and CD4-positive, primary T cells.

28. It would have been obvious to the ordinary artisan at the time the invention was made to make antibodies against CCR5 in order to inhibit HIV fusion to CD4 cells. The ordinary artisan would have been motivated to make these antibodies against the CCR5 chemokine receptor and have a reasonable expectation of success, given the knowledge that chemokines RANTES, MIP-1 α , and MIP-1 β , which are the natural ligands of CCR5, can inhibit HIV infection by blocking CCR5 chemokine receptor, as taught by Cocchi and Samson, and also given the knowledge that the antibody against the CXCR4 chemokine receptor can block HIV fusion, as taught by Berger. Using the analogy of an anti-CXCR4 antibody, thus, one of ordinary skill in the art would expect that an anti-CCR5 antibody that blocks the CCR5 receptor should also block HIV entry into CD4 cells via the CCR5 chemokine receptor. Moreover, since the CCR5 protein sequence was known at the time the invention was made, and since its G protein protein-coupled receptor structural feature was characterized by Samson, one of ordinary skill in the art knows how to make an antibody against the chemokine receptor by routine experiments as taught by Berger. It is also within the level of ordinary skill to synthesize fragments of the antibody capable of binding to the chemokine receptor. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

In response to Applicant's arguments:

29. Applicant argues that one of ordinary skill in the art would not have arrived at the claimed CCR5 antibody because Berger teaches an antibody against CXCR4, which is a receptor

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of T-cell tropic HIV strains, but not the claimed antibody against CCR5, which is a co-receptor for macrophage-tropic HIV strains.

30. In response to the Applicant's argument, the Office recognizes that Berger teaches an antibody against CXCR4, which is a receptor of T-cell tropic HIV strains, while the claimed antibody against CCR5 is a co-receptor for macrophage-tropic HIV strains. However, because both chemokine receptors CXCR4 and CCR5 are expressed on the surface of CD4 cells, one of ordinary skill in the art would recognize that the prior art anti-CXCR4 antibody against HIV fusion to CD4+ cells and the claimed anti-CCR5 antibody against HIV fusion to CD4 cells are functional equivalents although they target different chemokine receptors on CD4 cells.

31. Since Berger has shown that an antibody against chemokine receptor CXCR4 can inhibit HIV fusion to CD4+ T cells, it would have been obvious to one of skill in the art to substitute another antibody against other chemokine receptors used by HIV for entry into a CD4 cell, such as CCR5, to achieve the predictable result of inhibiting HIV fusion to a CD4 cells.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. **(Prior rejection- maintained-updated)** The rejection of Claims 51 and 57 under the non-statutory double patenting over Claims 1-9 and 33-38 of US Pat 7,122,185 (Application No. 10/371,483) **is maintained**. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant acknowledges the rejection and does not wish to prematurely respond.

33. **(New rejection-necessitated by new filing)** Claims 51 and 57 are rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over Claims 78-97 of co-pending Application 11/804,746 ('746) and Claims 78-107 of co-pending Application 11/805,573 ('573). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant Claims 51 and 57 are anticipated by co-pending Applications '746 and '573.

34. Claims 78-97 of co-pending Application '746 are directed to a composition comprising monoclonal antibody PA14 to CCR5.

35. Claims 78-107 of co-pending Application '573 are directed to a monoclonal antibody PA14 to CCR5.

35. The claim limitation of instant Application 09/888,938 clearly covers a genus of antibodies against CCR5, while Claims 78-97 of co-pending Application No. '746 and Claims

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78-107 of co-pending Application '573 are directed to a species of monoclonal antibody PA14 against CCR5. According to MPEP, a species will anticipate a claim to a genus. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (see MPEP 2131.02). In the instant case, the monoclonal antibody PA14 of co-pending Applications '746 and '573 (species) anticipates an antibody against CCR5 (genus) of instant Claims 51 and 57.

Remarks

36. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The Examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Bo Peng/
February 27, 2008